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Enclosed are comments submitted to the President's Council on Food Safety on behalf of Dr. Jim Cox, CEO of COX Technologies.

I have saved it as a text file. If for any reason you cannot open this file, please contact us immediately and we will re-send a different version. You may send a return email, nancyk@hkamarcom.com or call Hilary Kaye or Nancy Koprowski at (714) 426-0444.

Thank you very much.

Nancy Koprowski
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Attachment

February 14, 2000

U.S. Food and Drug Administration
Docket No. OPP-00550

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President's Council on Food Safety
Food Safety Strategic Plan

Risk Management Goal: The United States system for managing food safety is effective from farm to table.

Objective 2: Promote development and implementation of preventive techniques and controls using risk-based approaches and establishment of national standards, including performance

standards, where appropriate.

Time-Temperature Management Along the Cold Chain

Since the 1997 publication of President Clinton's National Food Safety Initiative, private industry has been developing and advancing new technologies to combat foodborne illness. Three years later, federal agencies should be asking the food industry what's stopping it from applying these new technologies as they become available following successful field-testing.

Food safety commands the attention of suppliers, retailers and consumers. Suppliers stress their conformance to governmental guidelines and seem committed to a policy of "we're covering our base" when it comes to the overall food safety problem. Retailers, as a group, have shown little initiative to install measures to ensure food protection and are often most concerned about the cost of such measures.

Both suppliers and retailers will point to effective measures to ensure sanitary operating procedures, but neither seems willing to tackle the biggest problem area: time-temperature management along the cold chain. The cold chain is the process of moving perishables from supplier to wholesaler to retailer to consumer.

Exposing food to unsafe temperatures is the single most significant problem in food protection, and "sell by" dates on perishable food items cannot tell the consumer if that food has been exposed to unsafe temperatures. Epidemiological and survey data confirm the most common source of foodborne pathogens is the practice of keeping foods for more than two to four hours at temperatures above 40(F. Outbreak statistics and survey data of foodborne illness show very strong seasonal dependence. Foodborne illness is rare in the months with cooler temperatures when the possibility of temperature abuse is reduced.

Food safety authorities recognize the temperature dependence of all foodborne illness, yet misinformation tends to suppress this vital observation. All species of foodborne microbes (such as *E. coli*) show temperature dependence in their growth characteristics. Effective time-temperature management can reduce the threat of foodborne illness.

The original National Food Safety Initiative called for "the development of in-package or on-package sensors to alert consumers of food not stored safely." This technology is ready for use at all levels of the food industry and is being marketed by several U.S. companies in a variety of configurations. Its benefits are well documented, extremely cost effective, and have been recognized by both the FDA and the USDA in suggested guidelines for food handling.

Time-temperature integrator tags (TTIs) placed on packages of "food at risk" are the best answer to the problem of temperature abuse. These easy-to-use labels can warn of temperature discrepancies on packages of perishables and enforce their removal from the distribution chain. There is no more effective way to eliminate temperature problems.

By now, food processors and retailers are familiar with TTIs. However, they still fear added costs and perceived problems with cooperation between vendor and purchaser. This stalemate will not solve itself, but rather requires technology-specific regulations.

Consumers have a right to know if the food industry is using the latest food safety technology to protect the world's food supply, and the government agencies overseeing food safety have a responsibility to make it happen.